IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

ANITA HOCHENDONER; EARL HOCHENDONER; ANITA BOVA; JOSEPH M. CARIK; BARBARA J. CARIK; AMBER BRITTON; SHAWN BRITTON; CHERYL BRITTON; THOMAS OLSZEWSKI; DARLENE COOKINGHAM; and DAVID ROBERTS, Individually and on behalf of all others similarly situated,	)	Civil Action No.
Plaintiffs,	)	JURY TRIAL DEMANDED
v.	)	
GENZYME CORPORATION; and MOUNT SINAI SCHOOL OF MEDICINE OF THE CITY UNIVERSITY OF NEW YORK,	)	
Defendants.	)	

COMPLAINT IN CIVIL ACTION

AND NOW come Plaintiffs Anita Hochendoner, Earl Hochendoner, Anita Bova, Joseph M. Carik, Barbara J. Carik, Amber Britton, Shawn Britton, Cheryl Britton, Thomas Olszewski, Darlene Cookingham, and David Roberts, individually and on behalf of others similarly situated, by and through their attorneys, Kurzweg Law Offices, C. Allen Black, Esq. and Matthew L. Kurzweg, Esq., and file this Complaint in Civil Action. In support thereof, Plaintiffs aver as follows:

PARTIES

1. Plaintiff Anita Hochendoner is an adult individual who currently resides in Pittsburgh, PA.

2. Plaintiff Earl Hochendoner is an adult individual who currently resides Pittsburgh, PA and is the

spouse of Anita Hochendoner.

3. Plaintiff Anita Bova is an adult individual who currently resides in Pittsburgh, PA.
4. Plaintiff Joseph M. Carik is an adult individual who currently resides in North Las Vegas, NV.
5. Plaintiff Barbara J. Carik is an adult individual who currently resides in Pittsburgh, PA and is the spouse of Joseph M. Carik.
6. Plaintiff Amber Britton is an adult individual who currently resides in Kirkland, WA.
7. Plaintiff Shawn Britton is an adult individual who currently resides in Seattle, WA.
8. Plaintiff Cheryl Britton is an adult individual who currently resides Seattle, WA and is the spouse of Shawn Britton.
9. Plaintiff Thomas Olszewski is an adult individual who currently resides in Grayling, MI.
10. Plaintiff Darlene Cookingham is an adult individual who currently resides in Grayling, MI and is the spouse of Tom Olzewski.
11. Plaintiff David Roberts is an adult individual who currently resides in Goldsboro, NC.
12. Defendant Genzyme Corporation ("Genzyme") is a corporation organized and existing under the laws of the State of Massachusetts, with its headquarters and principal place of business located at 500 Kendall Street, Cambridge, MA 02142, and doing business within the Western District of Pennsylvania and elsewhere in the United States.
13. Defendant Mount Sinai School of Medicine of the City University of New York ("Mt. Sinai") is a corporation organized and existing under the laws of the State of New York, with its headquarters and principal place of business located at One Gustave L. Levy Place, New York, NY 10029-6574. Mt. Sinai holds limited title to and is the sole licensor of U.S. Patent No. 5,356,804 to

Genzyme for the manufacture of Fabrazyme®.

JURISDICTION AND VENUE

14. Jurisdiction is conferred upon this judicial district pursuant to federal question jurisdiction under 28 U.S.C. §1331. This Court also has diversity jurisdiction pursuant to 28 U.S.C. § 1332(a) (1) because the Plaintiffs are citizens of a State different from one or more Defendants and the aggregate amount in controversy exceeds seventy five thousand ($75,000), exclusive of interest and costs. Jurisdiction is further conferred under 28 U.S.C. §§ 1331 and 1337. This Court also has diversity jurisdiction over the Classes (as hereinafter defined) pursuant to 28 U.S.C. §§ 1332(d) (2) and (6) of the Class Action Fairness Act of 2005 because one or more members of the Classes are citizens of a State different from one or more Defendants and the aggregate amount in controversy exceeds five million dollars ($5,000,000), exclusive of interest and costs.

15. Venue is proper in the Western District of Pennsylvania pursuant to 28 U.S.C. § 1391(a)(2) and(b)(2) because Defendants transact business within this district either by direct sale or underlying license agreements with three of the Plaintiffs, and injury to these three or more of the Plaintiffs occurred in this district.

16. Additional out-of-state Plaintiffs join the instant case under the Federal Rules of Civil Procedure Rule 20(a)(1)(A) and (B) as all injuries arose from a common fact and present a common question of law.

FACTUAL BACKGROUND

17. Plaintiffs Anita Hochendoner, Anita Bova, Joseph M. Carik, Amber Britton, Shawn Britton, Tom Olszewski, and David Roberts suffer from Fabry Disease, which is heritable genetic illness and

results in the body being unable to synthesize the enzyme alpha-galactosidase A, which is critical for the degradation and export of fats from cells.

18. Fabry disease is a life-threatening illness and without treatment results in the premature death of Fabry patients from complications such as renal disease, heart attack, and stroke.

19. Left untreated, Branton *et al.*, "Natural History and Treatment of Renal Involvement in Fabry Disease;" J. Am. Soc. Nephrol. 13:S139-S143 (2002) found from survival analysis that 50% of patients developed End Stage Renal Disease "ESRD" by 53 years, with a range of 21 to 56 years. Importantly, all patients in this National Institute of Health ("NIH") study who lived into their 50s developed ESRD.

20. While no cure for Fabry is yet available, one of the greatest breakthroughs in scientific research on Fabry disease has been the discovery that enzyme replacement therapy with agalsidase beta (Fabrazyme®) can effectively treat Fabry patients.

21. The scientific research on Fabry disease that led to the breakthrough was a direct result of taxpayer funding.

22. Specifically, the NIH awarded grant no. DK 34045 to Dr. Robert J. Desnick at the Mount Sinai School of Medicine of New York University to develop Fabrazyme® as an enzyme replacement therapy to treat Fabry Disease.

23. Mt. Sinai was granted U.S. Patent No. 5,356,804 to a method of producing agalsidase beta subject to the requirements and obligations of 35 U.S.C. §§ 200-212, commonly known as the Bayh-Dole Act.

24. Mt. Sinai exclusively licensed U.S. Patent No. 5,356,804 for the manufacture of agalsidase beta

(Fabrazyme®) to Genzyme Corporation, which is the sole supplier of the drug to the U.S. marketplace.

25. In April 2003, the Food and Drug Administration "FDA" granted approval for Genzyme to market Fabrazyme® for treatment of Fabry patients.

26. The FDA approval of Fabrazyme® was based on a recommended prescribed dose of 1 mg/kg body weight infused every two weeks as an intravenous (IV) infusion. See FDA approved package insert, attached hereto and incorporated herein as Exhibit A.

27. No other enzyme replacement therapy is approved in the U.S., although a slightly different molecule, designated agalsidase-alfa (Replagal®) is marketed overseas for treatment of Fabry disease.

28. From the date of approval until approximately June 2009, Genzyme was able to manufacture enough Fabrazyme® to treat all currently diagnosed Fabry patients in the U.S.

29. However, sometime before June 2009, Genzyme decreased production of Fabrazyme® as a result of a viral infection in their Allston Landing, MA manufacturing plant.

30. Genzyme caused the viral infection of Fabrazyme® by failing to clean and sterilize their bioreactors between production batches, and thus introduced the virus by cross-contamination.

31. Specifically, Genzyme would use the same bioreactors to produce both Fabrazyme® and a different biological drug, Cerezyme®, which is used to treat another enzyme deficiency termed Gaucher disease.

32. The Cerezyme® production batches were initially contaminated with the non-human Vesivirus 2117.

33. Genzyme then cross-contaminated Fabrazyme® cultures by failing to properly clean and sterilize the bioreactors before switching it for Fabrazyme® production

34. The Allston Landing facility was the subject of a FDA warning letter that followed an inspection in September and October of 2008. One of the FDA's concerns was controls to protect against microbial contamination,

35. Further, in November 2009, Genzyme produced Fabrazyme® vials that contained contaminants of particulate steel, glass and rubber.

36. The FDA initiated action against Genzyme which resulted in a consent decree in May 2010, which included a $175 million dollar fine and oversight of the manufacture of Fabrazyme® for at least 7 years.

37. In June 2009, as a direct result of its reduced production of Fabrazyme®, Genzyme unilaterally implemented a rationing plan for its reduced supply of Fabrazyme® for the then known Fabry patients, wherein Genzyme unilaterally limited then known Fabry patients to receiving only less than one-third (1/3) of the recommended prescribed dose ("Genzyme Rationing Plan").

38. By and through the Genzyme Rationing Plan, Genzyme also unilaterally barred any newly diagnosed patients from receiving Fabrazyme®.

39. Until about June 2009, Plaintiffs Joseph M. Carik, Anita Hochendoner, Anita Bova, David Roberts, and Tom Olszewski, and all other then known Fabry patients similarly situated, were receiving the recommended prescribed dose, but after June 2009, Genzyme reduced their respective doses to less than one-third of the FDA approved dose pursuant to the Genzyme Rationing Plan.

40. On or about January 2010, pursuant to the Genzyme Rationing Plan, Genzyme slightly increased doses to only 50% of the recommended prescribed dose to Plaintiffs Joseph M. Carik, Anita Hochendoner, Anita Bova, David Roberts and Tom Olszewski, and all other then known Fabry patients similarly situated.

41. As of this filing, almost two years after the Genzyme Rationing Plan began, Plaintiffs Joseph M. Carik, Anita Hochendoner, Anita Bova, David Roberts and Tom Olszewski as well as all other Fabry patients similarly situated in the United States being treated with Fabrazyme® do not receive the FDA approved dose from Genzyme as a direct result of the Genzyme Rationing Plan.

42. Plaintiffs Amber Britton and Shawn Britton were diagnosed with Fabry disease after June 2009.

43. Under the Genzyme Rationing Plan, after June of 2009, Genzyme barred all newly diagnosed Fabry patients from receiving any Fabrazyme®.

44. Under the Genzyme Rationing Plan, Genzyme barred Plaintiffs Amber Britton and Shawn Britton and all other Fabry patient similarly situated from receiving Fabrazyme®, despite immediate treatment with Fabrazyme® being medically indicated.

45. As of this filing, almost two years after the Genzyme Rationing Plan began, Genzyme still bars Fabrazyme® access to Plaintiffs Amber Britton and Shawn Britton and other United States citizens similarly situated and diagnosed with Fabry disease after June 2009.

46. Defendant Mt. Sinai knew of the Genzyme Rationing Plan, and despite having statutory duties to the contrary described hereinafter, with knowledge, consented to the Genzyme Rationing Plan under its exclusive license agreement with Genzyme.

47. Genzyme was aware of adverse events and/or the potential for such adverse events by reducing the

dose of Fabrazyme® below FDA approved levels.

48. Similarly, Mt. Sinai was also aware of adverse events and/or the potential for such adverse events associated with Genzyme's Rationing Plan, but consented and/or maintained consent for licensing the patent for Fabrazyme® despite having a duty to protect against the invention's unreasonable use and non-use under the Bayh-Dole Act.

49. Mt. Sinai was also aware that that Genzyme banned newly diagnosed patients from receiving Fabrazyme® and consented to Genzyme's banning the drug to new patients despite having a duty to protect against the invention's unreasonable use and non-use under the Bayh-Dole Act.

50. Mt. Sinai never informed the NIH of the Genzyme Rationing Plan and the resultant unreasonable use and non-use of the invention that was secured under the Bayh-Dole act, thereby concealing the violations of the Bayh-Dole act from the NIH.

51. Neither Mt. Sinai nor Genzyme has ever applied for regulatory approval of the Genzyme Rationing Plan or administration of a reduced Fabrazyme® dose to treat Fabry disease.

52. Neither Mt. Sinai nor Genzyme has ever shown that a reduced dose of Fabrazyme® is either safe or efficacious for treating Fabry disease.

53. Neither Mt. Sinai nor Genzyme has ever informed patients as to what adverse events have been observed or could result from the Genzyme Rationing Plan.

54. On October 22, 2010, the European Medical Agency ("EMA") issued a press release stating that "The [European Medicines Agency's Committee for Medicinal Products for Human Use] CHMP is now recommending that physicians switch back to prescribing the full dose of Fabrazyme

according to the authorised product information, depending on the availability of enzyme replacement therapy and the severity of the disease." See EMA recommendation for full dosage of Fabrazyme® for Fabry Patients, attached hereto and incorporated herein as Exhibit B.

55. The EMA's recommendation was based on the observation "that since the introduction of a lower dose of Fabrazyme in June 2009, there has been a steady increase in the number of reported adverse events, matching the increase in the number of patients on the lower dose. At first, most of the events were pain-related, soon followed by reports of events affecting the heart, the central nervous system and the kidneys." Id.

56. On November 16, 2010, the EMA publicly published a statistical study on the Fabrazyme supply shortage in Europe, which showed that patients not only had a return of life threatening symptoms but also an accelerated course of deterioration on the lowered dose. See EMA study attached hereto and incorporated herein as Exhibit C.

57. The EMA found that "In the early stages of the shortage the main increases in AEs [adverse events] were related to pain/paresthesia events, while later on in the shortage period, the main increases were in serious cardiac events such as myocardial infarction, in serious nervous disorders such as stroke, and – possibly to a lesser extent – in renal disorders. There have been consistent reports of a higher percentage of patients reporting peripheral pain, abdominal pain and diarrhoea on a daily basis after 25 June 2009 (start of the shortage)." Id.

58. Genzyme participated in the EMA study as part of its administration of the "Fabry Registry," a database collecting information on all Fabry patients, and Genzyme was aware of the EMA's results.

59. Genzyme did not and has not informed its patients of the results of the EMA study.

60. In August of 2010, Plaintiffs Joseph Carik, Anita Hochendoner, Anita Bova and Amber Britton requested that the NIH exercise its march-in rights under the Bayh-Dole Act to allow other manufacturers to enter the market to make Fabrazyme® under U.S. Patent No. 5,356,804.

61. On December 1, 2010, the NIH denied the petitioners' request stating that the three-year approval process for new manufacturers under FDA regulations render the Bayh-Dole remedy of march-in useless for alleviating drug shortages in a timely manner, despite the NIH recognition of the critical health need of patients for the drug.

62. As a direct result of the Genzyme Rationing Plan and/or Genzyme's denial of access to drug and/or sale of adulterated drug, Fabry patients have either had a return of symptoms, accelerated disease development, injury, and otherwise preventable disease progression, or have died during the shortage.

CLASS ALLEGATIONS

63. Paragraphs 1 through 62 are incorporated hereunder as though fully set forth at length.

64. Plaintiffs are bringing this action on behalf of themselves and all others similarly situated, which includes any and all individuals residing in the United States who have been diagnosed with Fabry disease, and their spouses ("Classes").

65. The proposed Classes are so numerous that joinder of all members of the Classes is impractical and the administration of the claims as set forth herein on behalf of the Classes is more efficient and will benefit the parties and the Court.

66. The questions of law and fact common to the Classes predominate over the questions affecting

only individual members of the Classes.

67. Plaintiffs' claims as set forth herein are typical of the claims of the Classes, as they have all suffered a similar harm as a result of the Defendants' actions and omissions.

68. Plaintiffs will fairly and adequately represent and protect the interests of the members of the Classes because their interests do not conflict with the interests of the individual members of the Classes. Plaintiffs have retained competent and experienced counsel to represent themselves and the members of the Classes.

69. Adjudication of the claims set forth herein as a class action is superior to individual litigation of the claims, which would be impractical, expensive, and unduly burdensome to the Court.

COUNT I: NEGLIGENCE

ANITA HOCHENDONER, ANITA BOVA, JOSEPH M. CARIK, DAVID ROBERTS, TOM OLSZEWSKI, AMBER BRITTON, AND SHAWN BRITTON, INDIVIDUALLY AND ON BEHALF OF ALL OTHER SIIMILARLY SITUATED v. GENZYME CORPORATION AND MOUNT SINAI SCHOOL OF MEDICINE OF THE CITY UNIVERSITY OF NEW YORK

70. Paragraphs 1 through 69 are incorporated hereunder as though fully set forth at length.

71. The injuries sustained by Plaintiffs were due to and were the direct and proximate result of the negligence, carelessness, and recklessness of Defendants Genzyme and Mt. Sinai generally, and under the following particulars:

a. in that Defendants failed to take reasonable steps to avoid and prevent viral contamination in the Genzyme Allston Landing, MA plant;
b. in that Defendants failed to take reasonable steps to avoid and prevent contamination of Fabrazyme® vials with particulate steel, glass and rubber;
c. in that the Defendants unilaterally devised, implemented, and/or approved with knowledge and consent the Genzyme Rationing Plan, and/or otherwise reduced or consented to reducing the dose of Fabrazyme® or denied it entirely for treatment of Fabry patients;

d. in that Defendants sold Fabrazyme® vials contaminated with glass, rubber and steel particles;

e. in that the Defendants designed and implemented and/or consented to the Genzyme Rationing Plan despite a statutory duty to ensure that Fabrazyme® was made available to all U.S. citizens and at the required dose pursuant to the Bayh-Dole Act's prohibition against non-use or unreasonable use of publically funded inventions under 35 U.S.C §200, specifically U.S. Patent No. 5,356,804;

f. in that the Defendants instructed and/or through knowledge and consent reduced the dose of Fabrazyme® to dangerous, sub-efficacious and unapproved levels;

g. in that the Defendants failed to test or require the testing of the effects of reducing the dosage of Fabrazyme® to unapproved levels to treat Fabry disease;

h. in that the Defendants failed to provide adequate warnings and/or cautions and/or directions concerning the dangers and limitations of the reduced dosage of Fabrazyme;

i. in that the Defendants failed to provide or require proper and/or adequate reserves of unadulterated Fabrazyme® in order to prevent or mitigate manufacturing errors;

j. in that the Defendants failed to provide or license a second source of manufacture for Fabrazyme® in order to prevent or mitigate life-threatening supply chain disruptions; and

k. in otherwise failing to exercise the care and caution that a reasonable, careful and prudent entity would have or should have exercised under the circumstances.

72. As a direct and proximate result of the negligence of Defendants, the Plaintiffs have sustained the following serious injuries, some or all which may be of a permanent nature:

a. renal injury;

b. cardiac injury;

c. neurological injury;

d. peripheral pain;

e. chronic abdominal pain and diarrhea;

f. impairment of vision;

g. impairment of hearing; and

h. premature death and other serious and permanent injuries.

73. As a direct and proximate result of the aforesaid injuries, Plaintiffs have been damaged as follows:

a. Plaintiffs have been and will be required to expend large sums of money for medical and surgical attention, medical and surgical supplies, medical and surgical appliances, and medicines;

b. Plaintiffs have suffered and will continue to suffer great pain, suffering, inconvenience, impairment of bodily function, and mental anguish;

c. Plaintiffs have been and will be deprived of earnings and earning capacity;

d. Plaintiffs have suffered loss of enjoyment of life;

e. Plaintiffs have died or suffered a reduced life expectancy; and

f. Plaintiffs' general health, strength and vitality have been impaired.

WHEREFORE, Plaintiffs Anita Hochendoner, Anita Bova, Joseph M. Carik, David Roberts, Tom Olszewski, Amber Britton, and Shawn Britton, individually and on behalf of all others similarly situated, demand judgment against Defendants, Genzyme Corporation and Mount Sinai School of Medicine of the City University of New York, jointly and severally in an amount in excess of $75,000.00, together with costs of suit. JURY TRIAL DEMANDED.

COUNT II: NEGLIGENCE *Per Se*

ANITA HOCHENDONER, ANITA BOVA, JOSEPH M. CARIK, DAVID ROBERTS, TOM OLSZEWSKI, AMBER BRITTON, AND SHAWN BRITTON, INDIVIDUALLY AND ON BEHALF OF ALL OTHER SIIMILARLY SITUATED v. GENZYME CORPORATION AND MOUNT SINAI SCHOOL OF MEDICINE OF THE CITY UNIVERSITY OF NEW YORK

74. Paragraphs 1 through 73 are incorporated hereunder as though fully set forth at length.

75. Defendants Genzyme and Mt. Sinai are strictly liable to Plaintiffs as follows under the Food, Drug, and Cosmetics Act 21 USC §351(a-d) regarding adulterated products, 21 USC §352(f) regarding adequate warning and labeling, 21 USC §355(j) regarding the statutory approval process for testing of previously unapproved doses, and 21 USC §356a(a) regarding testing required for substantial manufacturing changes; as well as being strictly liable under the Bayh-Dole Act 35 USC

§200 regarding the prohibition of unreasonable use or non-use of Bayh-Dole regulated inventions which are necessary for human health:

a. for restricting and/or consenting to restriction of administering Fabrazyme® at a dose that is below the FDA approved use of 1 mg/kg body weight infused every two weeks;
b. for failing to seek FDA approval for using the reduced dosage to treat Fabry disease;
c. for selling Fabrazyme® contaminated with glass, rubber and steel particles;
d. for failure to give adequate and complete warnings of the known or knowable dangers involved in the use Fabrazyme® at a reduced dose as required by FDA regulations;
e. for unreasonably using a publicly funded invention by restricting administration to below the FDA approved dose and for non-use of the invention by banning the publicly funded invention from being given to newly diagnosed Fabry patients;
f. for failing to provide or require proper and/or adequate reserves of unadulterated Fabrazyme® in order to prevent or mitigate manufacturing errors;
g. for failing to provide or license a second source of manufacture for Fabrazyme® in order to prevent or mitigate life-threatening supply chain disruptions; and
h. in otherwise failing to exercise the care and caution that a reasonable, careful and prudent entity would have or should have exercised under the circumstances.

76. By virtue of the negligence *per se* of Defendants, Defendants are liable for the severe injuries and conditions as set forth herein of Plaintiffs Anita Hochendoner, Anita Bova, Joseph M. Carik, David Roberts, Thomas Olszewski, Amber Britton, Shawn Britton, and all others similarly situated.

77. As a direct and proximate result of the aforesaid injuries, Plaintiffs Anita Hochendoner, Anita Bova, Joseph M. Carik, David Roberts, Tom Olszewski, Amber Britton, Shawn Britton, and all others similarly situated have suffered damages as set forth herein.

WHEREFORE, Plaintiffs Anita Hochendoner, Anita Bova, Joseph M. Carik, David Roberts, Tom Olszewski, Amber Britton, Shawn Britton, individually and on behalf of all others similarly situated, demand judgment against Defendants Genzyme Corporation and Mount Sinai School of Medicine of the

City University of New York, jointly and severally in an amount in excess of $75,000.00, together with costs of suit. JURY TRIAL DEMANDED.

COUNT III: STRICT LIABILITY

ANITA HOCHENDONER, ANITA BOVA, JOSEPH M. CARIK, DAVID ROBERTS, TOM OLSZEWSKI, AMBER BRITTON, AND SHAWN BRITTON, INDIVIDUALLY AND ON BEHALF OF ALL OTHER SIIMILARLY SITUATED v. GENZYME CORPORATION AND MOUNT SINAI SCHOOL OF MEDICINE OF THE CITY UNIVERSITY OF NEW YORK

78. Paragraphs 1 through 77 are incorporated hereunder as though fully set forth at length.

79. Defendants Genzyme and Mt. Sinai are strictly liable to Plaintiffs as follows:

    a. for failure to adequately and safely label the reduced dosage of Fabrazyme®;
    b. for selling and/or licensing the use of Fabrazyme® at a defective dose;
    c. for selling Fabrazyme® in a defective condition being adulterated with glass, rubber and steel particles;
    d. for selling and/or licensing the use of Fabrazyme® at a reduced dose when the dose is untested and unreasonably dangerous for its intended use; and
    e. for failure to give adequate and complete warnings of the known or knowable dangers involved in the use Fabrazyme® at a reduced dose.

80. By virtue of the strict liability of Defendants, Defendants are liable for the severe injuries and conditions as set forth herein of Plaintiffs Anita Hochendoner, Anita Bova, Joseph M. Carik, David Roberts, Thomas Olszewski, Amber Britton, Shawn Britton, and all others similarly situated.

81. As a direct and proximate result of the aforesaid injuries, Plaintiffs Anita Hochendoner, Anita Bova, Joseph M. Carik, David Roberts, Tom Olszewski, Amber Britton, Shawn Britton, and all others similarly situated have suffered damages as set forth herein.

WHEREFORE, Plaintiffs Anita Hochendoner, Anita Bova, Joseph M. Carik, David Roberts, Tom Olszewski, Amber Britton, Shawn Britton, individually and on behalf of all others similarly situated,

demand judgment against Defendants Genzyme Corporation and Mount Sinai School of Medicine of the City University of New York, jointly and severally in an amount in excess of $75,000.00, together with costs of suit. JURY TRIAL DEMANDED.

COUNT IV: BREACH OF WARRANTY

ANITA HOCHENDONER, ANITA BOVA, JOSEPH M. CARIK, DAVID ROBERTS, TOM OLSZEWSKI, AMBER BRITTON, AND SHAWN BRITTON, INDIVIDUALLY AND ON BEHALF OF ALL OTHER SIIMILARLY SITUATED v. GENZYME CORPORATION AND MOUNT SINAI SCHOOL OF MEDICINE OF THE CITY UNIVERSITY OF NEW YORK

82. Paragraphs 1 through 81 are incorporated hereunder as though fully set forth at length.

83. All of the resultant losses, damages and injuries sustained by Plaintiffs resulted directly and proximately from Defendants Genzyme's and Mt. Sinai's breach of express and/or implied warranties of merchantability or fitness for the use of Fabrazyme®, in the following particulars:

a. the Defendants failed to adequately, properly, and/or timely test the reduced dose prior to use;
b. Fabrazyme®, given at reduced dosage and/or being adulterated with glass, steel, and rubber particles, is not fit for the ordinary purpose for which it is customarily or foreseeably used;
c. the Defendants knew or should have known that the adulterated drug and/or reduced dosage of Fabrazyme® is dangerous and likely to cause damage to users;
d. Fabrazyme®, given at reduced dosage and/or being adulterated, was not of merchantable quality and was not in conformity, insofar as safety is concerned, with products used in a normal course of business and/or statutory mandates;
e. the Defendants knew or should have known that in order to make Fabrazyme® effective for its intended use, they should have provided the drug at the recommended dose;
f. the Defendants knew or should have known, that due to the inherently dangerous nature of the design of the dosing schedule and/or the drug adulteration, they should have provided warnings on the product to protect users;
g. the Defendants did not keep abreast of the state of the art in the science and/or knew of adverse events involving reduced dosage and failed to warn users;
h. the Defendants did not disclose to the users of the reduced dosage of Fabrazyme® that the

dosing was defectively and/or unreasonably designed, thereby making the product dangerous to use;

i. the Defendants knew or should have known that users were relying upon the expertise of the Defendants in designing, fabricating, manufacture, labeling and/or supplying Fabrazyme®;

j. in expressly or impliedly warranting that Fabrazyme® was in accordance with statutory mandates and efficacious; and/or

k. in expressly or impliedly misrepresenting that the reduced dose of Fabrazyme® was in accordance with statutory mandates and efficacious for use.

84. As a direct and proximate cause of the breach of these expressed or implied warranties, Plaintiffs Anita Hochendoner, Anita Bova, Joseph M. Carik, David Roberts, Thomas Olszewski, Amber Britton, Shawn Britton, and all others similarly situated suffered severe injuries and/or conditions as set forth herein.

85. As a result of their injuries and conditions, Plaintiffs Anita Hochendoner, Anita Bova, Joseph M. Carik, David Roberts, Thomas Olszewski, Amber Britton, Shawn Britton, and all others similarly situated have suffered damages as set forth herein.

WHEREFORE, Plaintiffs Anita Hochendoner, Anita Bova, Joseph M. Carik, David Roberts, Tom Olszewski, Amber Britton, Shawn Britton, individually and on behalf of all others similarly situated, demand judgment against Defendants Genzyme Corporation and Mount Sinai School of Medicine of the City University of New York, jointly and severally in an amount in excess of $75,000.00, together with costs of suit. JURY TRIAL DEMANDED.

COUNT V: VIOLATION OF BAYH-DOLE ACT PROSCRIPTION OF NON-USE OR UNREASONABLE USE OF PUBLICALLY FUNDED INVENTIONS (IMPLIED CAUSE OF ACTION)

ANITA HOCHENDONER, ANITA BOVA, JOSEPH M. CARIK, DAVID ROBERTS, TOM OLSZEWSKI, AMBER BRITTON, AND SHAWN BRITTON, INDIVIDUALLY AND ON BEHALF OF ALL OTHER SIIMILARLY SITUATED v. GENZYME CORPORATION AND MOUNT SINAI SCHOOL OF MEDICINE OF THE CITY UNIVERSITY OF NEW YORK

86. Paragraphs 1 through 85 are incorporated hereunder as though fully set forth at length.

87. The injuries sustained by Plaintiffs were due to Defendants Genzyme and Mt. Sinai violating the Bayh-Dole Act 35 U.S.C. §200, generally and under the following particulars:

a. in that the Defendants reduced the dose of Fabrazyme® or denied it entirely for Plaintiffs' Fabry disease thereby unreasonably using or/and not using the publicly-funded invention, U.S. Patent No. 5,356,804;

b. in that the Defendants instituted the drug ban for some citizens and rationing to other citizens despite a statutory duty to ensure that Fabrazyme® was made available to U.S. citizens and at the required dose pursuant to the Bayh-Dole Act's specific prohibition against a contractor's non-use and unreasonable use of publically funded invention under 35 U.S.C. §200;

c. in that the Defendants failed to require or provide adequate safeguards to prevent or mitigate damages resulting from the unreasonable use and non-use of publicly-funded invention, U.S. Patent No. 5,356,804;

d. in that the Defendants instituted the rationing and denial of access despite lacking title or other property right to any patent right of non-use or unreasonable use that otherwise may be allowed under 35 U.S.C. § 271(d)(4); and

in that the Defendants caused special injuries unique to the class arising out of the non-use and unreasonable use of the invention because the Plaintiffs have Fabry disease and rely on access to the publicly funded invention, Fabrazyme®, specifically to treat their disease, which is otherwise fatal.

88. By virtue of the violation of the Bayh-Dole Act, Defendants are liable for the severe injuries and conditions of Plaintiffs Anita Hochendoner, Anita Bova, Joseph M. Carik, David Roberts, Thomas Olszewski, Amber Britton, Shawn Britton, and all others similarly situated as set forth herein.

89. As a result of their injuries and conditions, Plaintiffs Anita Hochendoner, Anita Bova, Joseph M. Carik, David Roberts, Thomas Olszewski, Amber Britton, Shawn Britton, and all others similarly

situated have suffered damages as set forth herein.

WHEREFORE, Plaintiffs Anita Hochendoner, Anita Bova, Joseph M. Carik, David Roberts, Tom Olszewski, Amber Britton, Shawn Britton, individually and on behalf of all others similarly situated, demand judgment against Defendants Genzyme Corporation and Mount Sinai School of Medicine of the City University of New York, jointly and severally in an amount in excess of $75,000.00, together with costs of suit. JURY TRIAL DEMANDED.

COUNT VI: PENNSYLVANIA STATE LAW DECEPTIVE TRADE PRACTICE VIOLATION (73 P.S. §§201-1 - 201-9.2)

ANITA HOCHENDONER AND ANITA BOVA, INDIVIDUALLY AND ON BEHALF OF ALL OTHERS SIMILARLY SITUATED v. GENZYME CORPORATION AND MOUNT SINAI SCHOOL OF MEDICINE OF THE CITY UNIVERSITY OF NEW YORK

90. Paragraphs 1 through 89 are incorporated hereunder as though fully set forth at length.

91. All of the resultant losses, damages and injuries sustained by Plaintiffs resulted directly and proximately from Defendants Genzyme's and Mt. Sinai's deceptive acts or practices regarding the sale and use of Fabrazyme®, generally, and in the following particulars:

    a. failing to inform the Plaintiffs that the dosage given was below the certified and approved FDA use and/or the possible consequences of such unapproved use;
    b. affirmatively representing that the drug given at reduced dosage and/or contaminated with glass, rubber and steel particles is approved to successfully treat Fabry disease and/or Fabry disease patients will benefit from such use; and
    c. in expressly or impliedly misrepresenting that the reduced dose and/or adulterated Fabrazyme® was in accordance with statutory mandates and/or efficacious for use.

92. By the use of deceptive trade practices, Defendants are liable for the severe injuries and conditions of Plaintiffs Anita Hochendoner and Anita Bova, and all others similarly situated, as set forth

herein.

93. As a direct and proximate result of the aforesaid injuries, Anita Hochendoner and Anita Bova, and all others similarly situated, have suffered damages as set forth herein.

WHEREFORE, Plaintiffs Anita Hochendoner and Anita Bova, individually and on behalf of all others similarly situated, demand judgment against Defendants Genzyme Corporation and Mount Sinai School of Medicine of the City University of New York, jointly and severally in an amount in excess of $75,000.00, together with treble damages and costs of suit. JURY TRIAL DEMANDED.

COUNT VII: NEVADA STATE LAW DECEPTIVE TRADE PRACTICE VIOLATION (NEVADA REVISED STATUTES §§ 598.0903-0990)

JOSEPH M. CARIK INDIVIDUALLY AND ON BEHALF OF ALL OTHERS SIMILARLY SITUATED v. GENZYME CORPORATION AND MOUNT SINAI SCHOOL OF MEDICINE OF THE CITY UNIVERSITY OF NEW YORK

94. Paragraphs 1 through 93 are incorporated hereunder as though fully set forth at length.

95. All of the resultant losses, damages and injuries sustained by Plaintiff resulted directly and proximately from Defendants Genzyme's and Mt. Sinai's deceptive acts or practices regarding the sale and use of the drug, Fabrazyme®, generally, and in the following particulars:

    a. failing to inform the Plaintiff that the dosage given was below the certified and approved FDA use and/or the possible consequences of such unapproved use;
    b. affirmatively representing that the drug given at reduced dosage and/or contaminated with glass, rubber and steel particles is approved to successfully treat Fabry disease and/or Fabry disease patients will benefit from such use; and
    c. in expressly or impliedly misrepresenting that the reduced dose and/or adulterated Fabrazyme® was in accordance with statutory mandates and/or efficacious for use.

96. By the use of deceptive trade practices, Defendants are liable for the severe injuries and conditions of Plaintiff Joseph M. Carik, and all others similarly situated, as set forth herein.

97. As a direct and proximate result of the aforesaid injuries, Joseph M. Carik, and all others similarly situated, have suffered damages as set forth herein.

WHEREFORE, Plaintiff Joseph M. Carik demands judgment against Defendants Genzyme Corporation and Mount Sinai School of Medicine of the City University of New York, jointly and severally in an amount in excess of $75,000.00, together with punitive damages, and costs of suit. JURY TRIAL DEMANDED.

COUNT VIII: MICHIGAN STATE LAW DECEPTIVE TRADE PRACTICE VIOLATION (MICHIGAN COMPILED LAWS § 445.903 *et seq.)*

THOMAS OLSZEWSKI, INDIVIDUALLY AND ON BEHALF OF ALL OTHERS SIMILARLY SITUATED v. GENZYME CORPORATION AND MOUNT SINAI SCHOOL OF MEDICINE OF THE CITY UNIVERSITY OF NEW YORK

98. Paragraphs 1 through 97 are incorporated hereunder as though fully set forth at length.

99. All of the resultant losses, damages and injuries sustained by Plaintiff resulted directly and proximately from Defendants Genzyme's and Mt. Sinai's deceptive acts or practices regarding the sale and use of the drug, Fabrazyme®, generally, and in the following particulars:

a. failing to inform the Plaintiff that the dosage given was below the certified and approved FDA use and/or the possible consequences of such unapproved use;
b. affirmatively representing that the drug given at reduced dosage and/or contaminated with glass, rubber and steel particles is approved to successfully treat Fabry disease and/or Fabry disease patients will benefit from such use; and
c. in expressly or impliedly misrepresenting that the reduced dose and/or adulterated Fabrazyme® was in accordance with statutory mandates and/or efficacious for use.

100. By the use of deceptive trade practices, Defendants are liable for the severe injuries and conditions of Plaintiff Thomas Olzewski, and all others similarly situated, as set forth herein.

101. As a direct and proximate result of the aforesaid injuries, Thomas Olzewski, and all others similarly situated, have suffered damages as set forth herein.

WHEREFORE, Plaintiff Thomas Olszewski demands judgment against Defendants Genzyme Corporation and Mount Sinai School of Medicine of the City University of New York, jointly and severally in an amount in excess of $75,000.00, together with treble damages and costs of suit. JURY TRIAL DEMANDED.

COUNT IX: NORTH CAROLINA UNFAIR AND DECEPTIVE TRADE PRACTICES ACT VIOLATION (N.C. G.S. § 75-1.1 *et seq.*)

DAVID ROBERTS, INDIVIDUALLY AND ON BEHALF OF ALL OTHERS SIMILARLY SITUATED v. GENZYME CORPORATION AND MOUNT SINAI SCHOOL OF MEDICINE OF THE CITY UNIVERSITY OF NEW YORK

102. Paragraphs 1 through 101 are incorporated hereunder as though fully set forth at length.

103. All of the resultant losses, damages and injuries sustained by Plaintiff resulted directly and proximately from Defendants Genzyme's and Mt. Sinai's deceptive acts or practices regarding the sale and use of the drug, Fabrazyme®, generally, and in the following particulars:

a. failing to inform the Plaintiff that the dosage given was below the certified and approved FDA use and/or the possible consequences of such unapproved use;
b. affirmatively representing that the drug given at reduced dosage and/or contaminated with glass, rubber and steel particles is approved to successfully treat Fabry disease and/or Fabry disease patients will benefit from such use; and
c. in expressly or impliedly misrepresenting that the reduced dose and/or adulterated Fabrazyme® was in accordance with statutory mandates and/or efficacious for use.

104. By the use of deceptive trade practices, Defendants are liable for the severe injuries and conditions of Plaintiff David Roberts, and all others similarly situated, as set forth herein.

105. As a direct and proximate result of the aforesaid injuries, David Roberts, and all others similarly situated, have suffered damages as set forth herein.

WHEREFORE, Plaintiff David Roberts demands judgment against Defendants Genzyme Corporation and Mount Sinai School of Medicine of the City University of New York, jointly and severally in an amount in excess of $75,000.00, together with treble damages and costs of suit. JURY TRIAL DEMANDED.

COUNT X: LOSS OF CONSORTIUM

BARBARA J. CARIK, EARL HOCHENDONER, CHERYL BRITTON, AND DARLENE COOKINGHAM, INDIVIDUALLY AND ON BEHALF OF ALL OTHERS SIMILARLY SITUATED v. GENZYME CORPORATION AND MOUNT SINAI SCHOOL OF MEDICINE OF THE CITY UNIVERSITY OF NEW YORK

106. Paragraphs 1 through 105 of the Complaint are incorporated as if set forth fully at length herein.

107. As a direct and proximate result of the injuries sustained by their spouses, Plaintiffs have been damaged as follows:

a. Plaintiffs have been and will continue to be compelled to expend large sums of money for medical care, supplies, appliances, and medicine;
b. Plaintiffs have been and/or may be compelled to expend large sums of money for hiring help to perform household duties previously performed by their spouses; and
c. Plaintiffs have been and will be deprived of their spouse's aid, comfort, assistance, companionship, and consortium.

WHEREFORE, Plaintiffs Barbara J. Carik, Earl Hochendoner, Cheryl Britton, Darlene Cookingham, individually and on behalf of all others similarly situated, demands judgment against Defendants Genzyme Corporation and Mount Sinai School of Medicine of the City University of New

York, jointly and severally in an amount in excess of $75,000.00, together with treble damages and costs of suit. JURY TRIAL DEMANDED.

Respectfully submitted,

/s/ Matthew L. Kurzweg
Matthew L. Kurzweg, Esquire
Pa.I.D. 76462

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C. Allen Black, Jr., Esquire
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